DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District
Nashville Branch Office
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5380
Facsimile: 615-781-5391

April 5, 2004

Warning Letter No. 2004-NOL-19

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Charles C. Grissom, Owner
Alfresco Pasta
1138 Fourth Avenue South
Nashville, Tennessee 37210

Dear Mr. Grissom:

An inspection of your pasta manufacturing facility, located at 1138 Fourth Avenue South, Nashville, Tennessee, conducted by investigators of the Food and Drug Administration (FDA) on February 12 and 17, 2004, found significant deviations from seafood HACCP regulations [Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123)]. These deviations, which were previously brought to your attention in our letter dated May 8, 2003, cause your seafood products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the Seafood HACCP regulation through links in FDA's home page at http://www.fda.gov.

Our investigators found the following violations:

- You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.6(b). This applies to all of your seafood products.

- You must adequately monitor sanitation conditions and practices during processing, and maintain records of this to comply with 21 CFR 123.11(b) and (c). The inspection found sanitation monitoring records for one day in 2003 and three days in 2004. You must maintain records daily for all of your seafood products.

- You fail to have an individual who is trained in seafood HACCP principles to comply with 21 CFR 123.10. This is necessary to conduct a food hazard analysis, develop a HACCP plan, and review monitoring and sanitation records.

The above is not intended as an all-inclusive list of deviations. As a seafood processor, you are responsible for assuring that your plant operates in compliance with the Act, the seafood HACCP regulations and the Current Good Manufacturing Practice regulations in 21 CFR 110. You also

have the responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

You should take prompt action to correct these violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of the receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made and explain preventative measures to guard against future violations.

Your reply should be directed to Kari L. Batey, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,

Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483